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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/716,823 | 11/19/2003 | Robyn Sackeyflo | 50164/006004 | 7193 |

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| EXAMINER | |
|---|---|
| GEORGE, KONATA M | |
| ART UNIT | PAPER NUMBER |
| 1616 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/08/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/716,823 | SACKEYFLO ET AL. | |
| | Examiner | Art Unit | |
| | Konata M. George | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-42 and 59-61* is/are allowed.

6)☒ Claim(s) *1-4 and 43-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/9/06;6/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-61 are pending in this application.

### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on March 9, 2006 and June 5, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### *Action Summary*

2. The rejection of claims 7-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8-10, 15-17, 20 and 23-29 of US Patent 6,897,206 is hereby withdrawn as applicant has filed a terminal disclaimer.

3. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by International Journal of Dermatology is being maintained for the reasons stated in the previous office action.

4. The rejection of claims 5 and 6 under 35 U.S.C. 102(b) as being anticipated by Smith (5,900,249) is hereby withdrawn as applicant has amended the claims to overcome the reference.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by International Journal of Dermatology (1999).

The International Journal of Dermatology teaches a method of treating 349 patients with atopic dermatitis with a composition containing a tricyclic antidepressant and a corticosteroid. Of these 349 patients 90 were treated with a combination of triamcinolone (i.e. corticosteroid) and doxepin hydrochloride (i.e. antidepressant) (see abstract). It is also taught that 86 patients were treated with a combination of hydrocortisone and doxepin hydrochloride. Page 146, second column last paragraph teaches the composition is administered topically.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-4 and 43-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over the International Journal of Dermatology (1999).

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

The International Journal of Dermatology teaches a method of treating 349 patients with atopic dermatitis with a composition containing a tricyclic antidepressant and a corticosteroid. Of these 349 patients 90 were treated with a combination of triamcinolone (i.e. corticosteroid) and doxepin hydrochloride (i.e. antidepressant) (see abstract). It is also taught that 86 patients were treated with a combination of hydrocortisone and doxepin hydrochloride. Page 146, second column last paragraph teaches the composition is administered topically.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

The prior art does not teach the dosage amounts of the tricyclic antidepressant and a corticosteroid.

***Finding of prima facie obviousness***

***Rational and Motivation* (MPEP §2142-2143)**

With respect to the claimed dosage amounts, absent a clear showing of criticality, the determination of particular dosage amounts is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

***Response to Arguments***

7. Applicant's arguments filed March 9, 2006 have been fully considered but they are not persuasive.

Applicants have amended the claims to incorporated an intended use of the composition i.e. oral, rectal, intravenous, etc. Intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. In re Madder et al. 143 USPQ 248.

***Allowable Subject Matter***

8. Claims 5-42 and 59-61 are allowed. The prior art does not teach a composition comprising a tricyclic antidepressant selected from the group consisting of maprotiline, amoxapine, 8-hydroxyamoxapine, 7-hydroxyamoxpine, loxapine, 8-hydroxyloxapine,

clomipramine, desipramine, trimipramine, nortrityline or protriptyline together with a corticosteroid as the sole active ingredients. A method of treating an immunoinflammatory disorder comprising the same is also not taught.

***Conclusion***

9. Claims 1-4 and 43-58 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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